

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Image

In re Patent Application of

Atty Dkt. 1498-119

C# M#

SQUIRRELL et al.

TC/A.U.

1652

Serial No. 09/763,824

Examiner: Steadman, David

Filed: February 27, 2004

Date: March 1, 2004

Title: NOVEL ENZYME



Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE/AMENDMENT/LETTER

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

☒ **Correspondence Address Indication Form Attached.****Fees are attached as calculated below:**

| | | | | |
|--|----|----------------------|--------------|---------|
| Total effective claims after amendment | 0 | minus highest number | | |
| previously paid for | 20 | (at least 20) = | 0 x \$ 18.00 | \$ 0.00 |
| Independent claims after amendment | 0 | minus highest number | | |
| previously paid for | 3 | (at least 3) = | 0 x \$ 86.00 | \$ 0.00 |

| | |
|--|---------|
| If proper multiple dependent claims now added for first time, add \$290.00 (ignore improper) | \$ 0.00 |
|--|---------|

| | |
|--|---------|
| Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) (\$110.00/1 month; \$420.00/2 months; \$950.00/3 months) | \$ 0.00 |
|--|---------|

| | |
|---|---------|
| Terminal disclaimer enclosed, add \$ 110.00 | \$ 0.00 |
|---|---------|

| | |
|---|---------|
| <input type="checkbox"/> First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) (\$770.00) | \$ 0.00 |
| <input type="checkbox"/> Please enter the previously unentered, filed | |
| <input type="checkbox"/> Submission attached | |

| | |
|-----------------|----------------|
| Subtotal | \$ 0.00 |
|-----------------|----------------|

| | |
|--|----------|
| If "small entity," then enter half (1/2) of subtotal and subtract | -\$ 0.00 |
| <input type="checkbox"/> Applicant claims "small entity" status. <input type="checkbox"/> Statement filed herewith | |

| | |
|--|---------|
| Rule 56 Information Disclosure Statement Filing Fee (\$180.00) | \$ 0.00 |
|--|---------|

| | |
|------------------------------------|---------|
| Assignment Recording Fee (\$40.00) | \$ 0.00 |
|------------------------------------|---------|

| | |
|--------|------|
| Other: | 0.00 |
|--------|------|

| | |
|---------------------------|----------------|
| TOTAL FEE ENCLOSED | \$ 0.00 |
|---------------------------|----------------|

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

1100 North Glebe Road, 8th Floor
Arlington, Virginia 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100
BJS:

NIXON & VANDERHYE P.C.
By Atty: B. J. Sadoff, Reg. No. 36,663

Signature: _____



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Patent Application of

SQUIRRELL et al.

Atty. Ref.: 1498-119

Serial No. 09/763,824

Group: 1652

Filed: February 27, 2001

Examiner: Steadman, David

For: NOVEL ENZYME

* * * * *

March 1, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE

Responsive to the Office Action dated January 30, 2004, the applicants elect, with traverse, the subject matter of the Examiner's Group I and species Ia, for further prosecution in the above.

Reconsideration and withdrawal of the restriction requirement are requested for any of the following reasons.

The present application is a 371 U.S. national phase of PCT/GB99/03538. The principles of unity of invention, as opposed to U.S. restriction practice, apply.

The Examiner has artificially, and without basis in the Rules, attempted to define as "special technical features" of the claimed subject matter, the reference sources of the claimed variants, i.e., *Photinus pyralis* (Group I), *Luciola mingrelica* (Group I), *L. cruciata* (Group III), *L. lateralis* (Group IV), *Hotaria paroula* (Group V), *Pyrophorous plagiophthalmus* (Group VI), *Lampyrus noctiluca* (Group VII), *Pyrocoelia nayako*

(Group VIII), and *Photinus pennsylvanica* (Group IX). Within Groups (I) – (IX), the Examiner has asserted that 8 separate inventions are defined within Group I, 8 separate inventions are defined within Group II, 8 separate inventions are defined within Group III, and 8 separate inventions are defined within Group (IV), corresponding to individually disclosed mutations. Further, the Examiner has asserted that plants of claim 26 define 37 separately patentable inventions. (Claim 27, while indicated as pending, is not included in any of the Examiner's Groups. In fact, claim 27 was canceled by way of a Preliminary Amendment filed February 27, 2001.)

The only articulated basis for the Examiner's assertion of lack of unity of invention is reliance of "Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions" and a conclusion that the claimed "polypeptides are not regarded as being of similar nature because all alternatives do not share a common structure." See, page 9 of the Office Action dated January 30, 2004 (Paper No "01232004", as referred to in the footer of page 1 of the Office Action).

The Examiner provides no technical or scientific support for his conclusion.

Section (f) of Annex B of the PCT Administrative Instructions (hereinafter "Annex B") provides as follows:

(f) "**Markush Practice.**" The situation involving the so-called "Markush practice" wherein a single claim defines alternatives (chemical or non-chemical) is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) all alternatives have a common property or activity, and
- (B)
 - (1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or
 - (B)
 - (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.
- (ii) In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together.
- (iii) In paragraph (f)(i)(B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.
- (iv) The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.
- (v) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.

The Examiner admits that the claimed polypeptides "share a common property or activity." See, page 9 of Paper No. 01232004. The requirement of Section (f)(i)(A) of Annex B is admitted by the Examiner to be met.

The claimed polypeptides, and other aspects of the claimed invention based thereon, share a common structure (i.e., "a significant structural element is shared by all of the alternatives"). Specifically, the Examiner is urged to appreciate that

luciferases, i.e., the proteins of the claimed invention, are highly conserved as a group of proteins. Moreover, luciferases are obtainable from a limited number of sources. All known luciferases share a very high degree of homology with one another, as is clear from Ye et al., *Biochimica et Biophysica Acta*, 1339 (1997) 39-52 (copy attached), which is referenced on page 1 lines 22 to 24 of the specification. It is clear from Ye et al., and in particular from Figure 2 of the same, that there are many motifs within the luciferase proteins that are common to all known luciferases, indicated by dark shading, as well as many other motifs which contain only conservatively substituted amino acid residues. Therefore the basis for the Examiner's restriction requirement is not well founded and the Examiner's lack of unity conclusion should be withdrawn.

The applicants note, for completeness, that even the U.S. Patent Office has previously recognized that luciferases from different sources (i.e., the basis for the present Examiner's unity objection) share a common structure. Specifically, the Examiner is requested to see the claims of the attached U.S. Patent No. 6,132,983, which provides luciferases generally.

The present applicants set out to identify luciferases which have an improved property, i.e., enhanced thermostability, and this was achieved by defining a group of specific amino acid residues within the protein which impact on the thermostability, of these conserved proteins. The particular residues can be precisely identified by their common position in the protein structures. It is believed that this is further evidence of the common structure found amongst this protein group.

As a result, the applicants submit that the restriction requirement is unjustified and the claims define a common special technical feature.

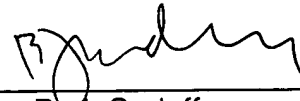
SQUIRRELL et al.
Serial No. **09/763,824**
March 1, 2004

Withdrawal of the restriction requirement and an Action on the merits of the full
breadth of the claimed invention are requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



B. J. Sadoff
Reg. No. 36,663

BJS:pp
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100